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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,352

02/27/2006

Albert Schomig

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5048

57360

7590

04/02/2010

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EXAMINER

GANESAN, SUBA

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

04/02/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,352	Applicant(s) SCHOMIG ET AL.	
	Examiner SUBA GANESAN	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,21-28 and 31-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,21-28 and 31-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/9/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 2/9/2010 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 1, 3-6, 21-28, 31-42 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims **1, 3-6, 21-28, 31-42** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The term "to a predetermined extent" in claim 1, 34, and 39 is a relative term which renders the claim indefinite. The term "predetermined extent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Appropriate correction is requested.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims **1, 3, 5-6, 34-35** are rejected under 35 U.S.C. 102(b) as being anticipated by Yan (U.S. Pat. No.: 5,843,172).

8. Yan discloses a stent system for placement in a body lumen which is expandable from a contracted state to an expanded state (col. 1 lines 5-10), comprising: a stent having a roughened exterior surface (fig. 1 and 2), wherein at least a portion of the exterior surface is roughened to a predetermined extent for coating (see fig. 2). The entire stent wire is porous, therefore it is expected that the inner and side surface of the stent are roughened to a predetermined extent (col. 4 lines 23-27). Yan further discloses a polymer-free external coating consisting of a therapeutic agent disposed directly on the exterior of the stent (col. 2 lines 15-38). The stent is stainless steel (col. 4 line 33). The stent is balloon expandable (col. 8 lines 1-2). The stent can be annealed (col. 4 lines 37-39).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims **4, 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan (U.S. Pat. No.: 5,843,172) in view of Sirhan (Pub. No.: US 2002/0082679).
3. Yan is explained supra. Yan further teaches the use of the drug stent to treat restenosis (col. 1 lines 12-30). However, Yan lacks specific disclosure of the drug Tacrolimus. Sirhan is also concerned with restenosis (see abstract) and teaches the use of tacrolimus as a suitable drug for therapeutic treatment (para. 30). Selecting a known material based on its suitability for an intended use is considered within the level of ordinary skill of a worker in the art (see MPEP 2144.07). Therefore, it would have been obvious at the time the invention was made to have provided the stent of Yan with the specific drug Tacrolimus, as taught by Sirhan, for the purpose of treating restenosis with a suitable therapeutic agent.
4. Claims **21-28, 37-40**, and **42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan (U.S. Pat. No.: 5,843,172) in view of Callol et al. (U.S. Pat. No.: 6174329).
5. Yan is explained supra. However, Yan lacks a stent that is sandblasted to create surface roughness. Sandblasting with sand, glass beads, or corundum is considered a product-by-process limitation that is not given patentable weight in the absence of distinguishing structure (See MPEP 2113). Because both the Yan

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stent and a sandblasted stent result in the structure of a rough-surface stent, the specific process claimed to achieve Applicant's rough surface is not required to meet the claim.

6. Alternatively, Callol teaches the use of sandblasting as a suitable means for roughening a stent surface (col. 7 lines 23-27) in order to improve adhesion between layers. Therefore, if a sandblasted surface is not equivalent to the surface of Yan, it would have been obvious to utilize sandblasting as the means to roughen the stent surface for the purpose of improving adhesion between the stent surface and the therapeutic agent. The use of sand, glass, or corundum would have yielded equivalent sand-blasted surfaces; consequently these specific materials are considered part of a product-by-process limitation. Callol teaches coating the inner and outer surfaces of a stent (see fig. 6).

7. Claims **31-33** and **41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan (U.S. Pat. No.: 5,843,172) in view of Callol et al. (U.S. Pat. No.: 6174329).

8. Yan in view of Callol is explained supra. However, the combination lacks specific teaching for the drug Tacrolimus. Sirhan teaches the use of tacrolimus as a suitable drug for therapeutic treatment (para. 30). Selecting a known material based on its suitability for an intended use is considered within the level of ordinary skill of a worker in the art (see MPEP 2144.07). Therefore, it would have been obvious at the time the invention was made to have provided the stent

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of Yan with the specific drug Tacrolimus, as taught by Sirhan, for the purpose of treating restenosis with a suitable therapeutic agent.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Wu et al. **(6,805,898)**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774